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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,651	06/20/2002	Jerome Michel Jacques Bibette	0512-1023	2772

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EXAMINER

METZMAIER, DANIEL S

ART UNIT	PAPER NUMBER
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1712

DATE MAILED: 07/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/088,651	Applicant(s) BIBETTE ET AL.	
	Examiner Daniel S. Metzmaier	Art Unit 1712	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-37 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-20, 23 and 26-37 is/are rejected.
- 7) ☐ Claim(s) 21, 22, 24 and 25 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 18-37 are pending.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 18-20, 23, and 26-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Centre National De La Recherche Scientifique, WO 99/07463 (hereafter WO 99/07463), as evidenced by family member of Bibette et al, US 6,627,603, in view of Bibette et al, US 5,938,581 (all of record).

Bibette et al, US 6,627,603, is employed as an English language translation of the WO 97/38787 reference. The disclosures are deemed to be the same or substantially the same as based on the PCT application.

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Bibette et al, US 5,938,581, is employed as an English language translation of the WO 97/38787 reference. The disclosures are deemed to be the same or substantially the same as based on the PCT application. The US patents are referred to for citations hereafter.

WO 99/07463 and Bibette et al '603 (abstract; column 4, lines 52 et seq and 67 et seq; column 5, lines 8-9, 20, and 31-35; and claims) disclose releasing an active principle from multiple emulsions. WO 99/07463 and Bibette et al '603 (column 4, lines 67 et seq; particularly column 5, lines 8-9, 20, and 31-35; and claims) disclose the use of alkylene oxide copolymers as water-soluble hydrophilic agents among other surfactants, polyglycerol polyricinoleate as a fat-soluble surfactant and disclose hydrophilic active agents from the same fields of endeavor as applicants instantly claimed hydrophilic active agents.

The claim 23 alkylene oxide copolymers are known water soluble hydrophilic alkylene oxide copolymers (Sold under the trademark Pluronic®).

The monodispersed emulsions disclosed and exemplified read on applicants polydispersity of 30% or less, which applicants identify as monodispersed. An ideal monodispersed system would have a polydispersity approaching zero.

WO 99/07463 and Bibette et al '603 (Example 2) discloses the formation of monodispersed double emulsions in a two stage process, wherein a polydispersed W/O emulsion is converted to a monodispersed emulsion under controlled gentle shearing followed by incorporation into an outer aqueous phase. The polydispersed double

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emulsion would have existed prior to the microfluidizer treatment (column 7, line 31 et seq).

WO 99/07463 and Bibette et al '603 (column 4, lines 52-63) disclose the release of the active principle from the internal phase (A2) may be induced by a compound already in the external environment. WO 99/07463 and Bibette et al '603 further (column 4, lines 59-62) state: "this agent can in particular be . . . or alternatively a hydrocolloid, such as xanthan gum, guar, or carrageenan, and their derivatives." Said hydrocolloids are polysaccharides.

Since the WO 99/07463 and Bibette et al '603 references disclosure of "This agent" appears to be referring to the "alternatively a compound" set forth in the preceding paragraph, the xanthan gum, guar, or carrageenan, and their derivative would have been present in "the external environment" that includes the outer phase A2. The reference does not distinguish between the "the external environment" and the A2 phase.

To the extent the WO 99/07463 and Bibette et al '603 references differ from the claims in the concentrations of the hydrocolloids, said concentrations would have been obvious in view of the hydrocolloids are known thickening agents and emulsions having sufficiently high concentrations would become solids and/or gels. Concentrations higher than 10 % by weight would not have been expected already in the external environment based on their thickening properties.

Bibette et al '581 discloses making emulsions from polydispersed emulsions to form a monodispersed emulsion employing controlled shearing. Bibette et al '581

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(column 4, lines 17 et seq) disclose the formation of viscoelastic compositions by the further addition of a thickener, such as dextran, where the surfactant does not provide the appropriate viscoelastic effect.

These references are combinable because they teach monodispersed emulsions and methods of making. It would have been obvious to one of ordinary skill in the art at the time of applicants' invention to employ the methods of Bibette et al '581 in making the emulsions of WO 99/07463 and Bibette et al '603 to form the monodispersed emulsions taught therein as an obvious conventional shearing method of converting a polydispersed system to a monodispersed system.

Allowable Subject Matter

4. Claims 21-22 and 24-25 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

5. Applicant's arguments filed April 11, 2006 have been fully considered but they are not persuasive.

6. Applicants (pages 2 and 3) assertions that the WO '463 and US '603 fail to disclose the 50 to 95% of aqueous phase in the Ei is not deemed persuasive since claim 9 of '603 specifically includes 50% of aqueous phase in 50 % continuous phase of Ei.

7. Regarding applicants arguments of the addition of polysaccharides, WO 99/07463 and Bibette et al '603 further (column 4, lines 59-62) state: "this agent can in

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particular be . . . or alternatively a hydrocolloid, such as xanthan gum, guar, or carrageenan, and their derivatives.” Said hydrocolloids are polysaccharides.

The WO 99/07463 and Bibette et al ‘603 emulsions are characterized as metastable with the advantage of controlled release of the actives. The instant claims do not exclude the emulsions as characterized in the WO 99/07463 and Bibette et al ‘603 references.

Applicants’ arguments regarding the function of the thickeners have not been deemed persuasive since the claims do not make this distinction and add the same materials in overlapping concentrations. It is further noted that the claims recite further osmotic balancing agents. The establishment of an osmotic balance is clearly known in the art as shown at least in the WO 99/07463 and Bibette et al ‘603 as critical.

8. Applicants’ (page 4) arguments that the reference are not combinable has not been deemed persuasive since the references are directed to controlled release and active delivery compositions. The fact that the references teach specific modifications for specific effects in the same field of endeavor render said references particularly pertinent one to the other.

Furthermore, the use of the various thickening agents are derived from natural materials having different thickening effect. Claims directed to the compositions having the properties asserted by applicants have been indicated as allowable.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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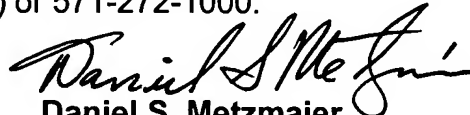
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel S. Metzmaier whose telephone number is (571) 272-1089. The examiner can normally be reached on 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Randy P. Gulakowski can be reached on (571) 272-1302. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Daniel S. Metzmaier
Primary Examiner
Art Unit 1712

DSM